REMARKS

Status of Claims

In the Office Action, the Examiner indicated that claims 1 through 68 are pending in the application and the Examiner rejected all claims. Claims 1-23, 46, 52, and 66 are canceled. Claims 24, 47-50, and 56 are amended. Accordingly, Claims 24-45, 47-51, 53-65, 67, and 68 are pending.

Discussion of Claim Amendments

Claim 24 has been amended to delete the term "blood" from the phrase "blood donor" as the antecedent basis is not limited to a "blood donor." Claims 47 and 48 are amended to avoid depending on canceled claims. Claim 49 is amended to recite that the biological sample is taken from "at least on donor from at least one collection establishment." This amendment is supported, for example, by original claim 24. Claim 50 is amended to be consistent with the amendment to claim 49. Claim 56 is amended to correct a dependency.

Claimed Invention

As amended, the claimed invention relates to a method for identifying a research subject in a group of donors from a collection establishment. This method involves obtaining a biological sample and medical data from such donors to create a database from which research subjects can be identified by screening the database for identifying criteria. The claimed invention also relates to a method of creating a database by collecting a biological sample and

medical data from a donor from a collection establishment that includes proteomic and genomic information from the sample. The claimed invention further relates to using this database to identify genomic and proteomic characteristics which correlate with a disease.

Applicants' claimed methods leverage the sample and data collecting capabilities of collection establishments which have not been traditionally involved in identifying research subjects. By using collection establishments to gather medical data and biological samples, the pharmaceutical industry can gain access to an ethnically diverse population that is not limited to patients suffering from particular diseases. Given that many donors are repeat donors, this method also allows for the collection of biological samples and medial data longitudinally. Another advantage of using collection establishments is that they typically have long-term sample storage infrastructure for storing biological samples. A database generated from longitudinal medical data and testing of longitudinal biological samples from a diverse population may help identify genomic and proteomic characteristics which correlate with a disease.

Discussion of Prior Art References

Each of the Examiner's obviousness rejections relies on U.S. Patent No. 5,991,729 to Barry et al. in combination with one or more of the following patents U.S. Patent No. 6,368,797 to Schappert; U.S. Patent No. 5,626,144 to Tacklind et al.; U.S. Patent No. 5,915,240 to Karpf; or U.S. Patent No. 6,730,477 to Sun et al. These patents are each discussed in turn below in the order in which they were cited in the Examiner's Action.

U.S. Patent No. 5,991,729 to Barry et al.

U.S. Patent No. 5,991,729 to Barry et al. ("Barry") teaches methods for generating a document that contains medical information specific to a patient to aid in medical counseling. As shown in Figures 1 and 2, a biological sample is taken from a patient, analyzed, and a diagnostic code and a description of the analysis of the sample are entered into a relational database. A report can be generated from the database that retrieves archived textual and graphical information specific for the entered diagnostic code and compiles a report specific to a particular patient. Accordingly, Barry is directed to method of creating an individualized medical report based on entering a diagnostic code into a relational database which contains archived information for each diagnostic code. Barry is not directed to a method for creating a database of medical data from donors nor is Barry directed to a method for identifying research subjects from such a database.

U.S. Patent No. 6,368,797 to Schappert

U.S. Patent No. 6,368,797 to Schappert ("Schappert") teaches a method for treating or identifying patients at risk for neurological diseases, especially Alzheimer's, based on testing for allelic variants of GPIIIa or GPIIb and forecasting the outcome/suitability for entering patients into clinical drug trials. The invention in Schappert is based on the realization that patients with Alzheimer's were almost four times more likely to have mutations in both the GPIIIa and GPIIb

allele. Schappert is not directed to creating a database of medical data from donors nor is Schappert directed to method for identifying a research subjects from such a database.

U.S. Patent No. 5,626,144 to Tacklind et al.

U.S. Patent No. 5,626,144 to Tacklind et al. ("Tacklind") teaches a system to monitor a patient with a disease state such as, for example, asthma. The system sends data to a remote computer system which records longitudinal data, and time stamps this data. Tacklind describes an asthma monitoring system and the use of a relational database to store information on a patient, using longitudinal data in the form of measured values with time stamps. The data can then be put into a report format and provided to a physician. Tacklind does not disclose using a database to identify a research subject.

U.S. Patent No. 5,915,240 to Karpf

U.S. Patent No. 5,915,240 to Karpf ("Karpf") teaches a reference computer system for access to medical information over a computer network. The network includes a number of elements: a medical look-up "client" program, a medical look-up "server" program, and a medical "call server". The server provides a central database for a single type of medical information. The client program maintains a local database for a variety of types of medical information. The client program automatically updates itself from the servers. A network chat facility (med call) allows the user to engage in real-time communication with a person at a help site who can provide assistance to the user. For example, the reference computer system can be

used to look up medical information that must be up-to-date and current such as blood donor deferral criteria. Karpf does not teach creating a database of medical data from donors much less using such a database to identify research subjects.

U.S. Patent No. 6,730,477 to Sun et al.

U.S. Patent No. 6,730,477 to Sun et al. ("Sun") is directed to methods for diagnosing, monitoring and staging breast cancer based on analyzing changes in levels of breast specific genes (BSG) in cells. Sun does not teach creating a database of medical data from donors much less using such a database to identify research subjects.

Discussion of Obviousness Rejections

The Examiner has asserted the same ten § 103 obviousness rejections as asserted in the prior Office Action dated January 4, 2006 even though some of the claims had been amended. For example, although applicants' amended claim 46 to depend from claim 1, the Examiner applied the same rejection to claim 46 even though the claim now encompasses all the limitations from claim 1. An "examiner must consider the information submitted with the applicant's reply and apply the information as the examiner deems appropriate." M.P.E.P. § 7.04.14(b). Accordingly, applicants request respectfully that the Examiner fully consider the amendments made to date in this application.

Applicants submit that the Examiner has failed to establish a *prima facie* showing of obviousness, and that the claimed invention is patentably distinct over the references cited.

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2143.

Here, the combination of references applied by the Examiner do not teach or suggest all the claim limitations and do not provide any motivation for combining the references. None of the art cited by the Examiner alone or in combination provides a method for identifying a research subject in a group of donors from at least one collection establishment or a method of creating a database by collecting a biological sample and medical data from a donor from a collection establishment that includes proteomic and genomic information from the sample. This is because the following art relied upon by the Examiner is directed to fundamentally different types of medical databases for fundamentally different purposes as summarized below:

Barry	a relational database for matching archived medical information to particular diagnosis codes and generating a specific patient report;
Schappert	a database of similarly afflicted subjects (Alzheimer's) containing the GPIIIa and GPIIb genotypes and other health data for determining how to treat a similarly afflicted patient;
Tacklind	a relational database for pairing a patient ID with measured values that have been remotely recorded and generating reports of the measured values; and

Karpf	a database for storing up-to-date medical information that can be accessed by remote systems.

Each of the Examiner's rejections is addressed independently below.

Claims 1, 4, 6-9, 11-14, 16, 21-24, 28-30, 33-36, 38, 42-44, and 66-67

The Examiner has rejected claims 1, 4, 6-9, 11-14, 16, 21-24, 28-30, 33-36, 38, 42-44, and 66-67 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,991,729 to Barry in view of U.S. Patent No. 6,368,797 to Schappert. Claims 1-23 and 66 have been canceled.

Neither Barry nor Schappert disclose identifying a research subject in a group of donors from at least one collection establishment

Claim 24, the only remaining independent claim included in this rejection, is directed to a method for "identifying a research subject in a group of donors from at least one collection establishment" based on obtaining a biological sample and medical data from a donor and matching this data with criteria for a research project "in order to identify a research subject." As discussed above neither Barry nor Scheppert discloses collecting biological samples or medical data from donors to form a database to be used "in order to identify a research subject."

To support the §103 rejection of claim 24, the Examiner states that "As per claim 24, Barry et al. teaches a method for identifying a research subject in a group of donors from at least one collection establishment." This is a mischaracterization of Barry, and the Examiner has not provided a citation for this assertion. Barry is directed simply to generating a patient specific report by matching a diagnosis code or an analysis of a sample with archived textual and

graphical medical information relevant to that patient's diagnosis. The methods of Barry are not used to identify potential research subjects, but instead are used to provide a medical report to a patient to aid the patient in treating and understanding his disease state.

In order to avoid the conclusion that neither Barry nor Schappert disclose "identifying a research subject in a group of donors from at least one collection establishment," the Examiner asserts that this

> limitation is part of the preamble in the claims and therefore this limitation has not been given patentable weight where it merely recites the purposes of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. Office Action at p. 12.

Contrary to the Examiner's assertion, however, identifying a research subject is an integral part of claim 24.

Claim 24 recites as the last step "matching the identifier from the first database with the name and contact information *in order to identify a research subject.*" Accordingly, "identifying research subjects" must be given patentable weight as it occurs in the body of the claim.

Moreover, as per M.P.E.P. § 2111.02, "if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Here, it is clear that the preamble is more than a statement of the intended use of a structural device, but rather is a statement of the intentional purpose for which the method must be performed, particularly as the last step refers to this purpose. See, e.g., *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003), *cited* in M.P.E.P. § 211.02, (In a claim directed to a method of treating or preventing pernicious anemia

in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the preamble is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. Thus the claim is properly interpreted to mean that the vitamin preparation must be administered to a human with a recognized need to treat or prevent pernicious anemia.).

Moreover, neither Barry nor Schappert disclose collecting biological samples and medical data from *donors of collection establishments* in order to generate a database for identifying research subjects. Barry merely collects data from a single patient in order to generate a report specific to that patient. Schappert discloses testing for specific variant alleles from a limited patient population, subjects diagnosed with Alzheimer's diseases and age-matched healthy individuals.

Accordingly, because neither Barry nor Schappert disclose "identifying a research subject in a group of donors from at least one collection establishment," this obviousness rejection must be withdrawn.

Neither Barry nor Schappert disclose matching a donor's medical data with certain criteria for a research project

The cited art also fails to meet the claimed requirement of matching the donor's medical data with certain criteria for a research project. The Examiner concedes that Barry does not disclose "identifying criteria for selecting a research subject" or "extracting an identifier from the first database, wherein said identifier is associated with a donor matching the identified criteria." Office Action at p. 4. To overcome this gap, the Examiner cites to Col. 12, ln. 39-52 of Schappert which reads:

> Accordingly, a subject may be characterized as a candidate for prophylactic therapies that can delay, inhibit, or prevent degenerative neurological symptoms. Further, either alone or in combination with other health data, the variant GPIIIa and GPIIb alleles can be used to predict a subject's outcome by comparing the subjects GPIIIa and GPIIb genotypes (and other health data) to a patient database containing the GPIIIa and GPIIb genotypes (and other health data) of similarly afflicted subjects. Based on this database comparison, a subject's likely outcome, i.e., progression of disease, cure rate, response to therapy, morbidity and mortality, can be statistically assessed.

As seen in this quote, the focus is not on the identification of research subjects from a pool of donors from collection establishments as in claim 24, but instead on using genomic information from one subject and comparing this patient's genotype to a patient database of *similarly afflicted* subjects. In stark contrast, Claim 24 and its dependents are directed to identifying criteria for selecting a research subject and using these criteria to identify a matching donor. Conversely, Schappert uses its criteria (GPIIIa and GPIIb alleles) by comparing it to data from *similarly afflicted* subjects for prognosis/treatment of Alzheimer's disease. Thus, the method does not involve *identifying* research subjects by using certain criteria but rather taking an *already identified subject* and determining what therapies would be most efficacious by comparing certain criteria to similarly afflicted subjects. In view of the above, applicants respectfully request the Examiner to reconsider and withdraw the rejection.

Claims 2 and 25

The Examiner has rejected claims 2 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24 above, respectively.

Claim 2 is canceled. Claim 25 depends on claim 24, and recites that informed consent is obtained from the subject. Given the patentability of claim 24 based on the arguments above, applicants request this rejection be withdrawn.

Claim 3

Claim 3 is canceled. Accordingly, this rejection is moot.

Claim 46

Claim 46 is canceled. Accordingly, this rejection is moot.

Claim 48

The Examiner has rejected claim 48 under 35 U.S.C. §103(a) as being unpatentable over Barry in view of Tacklind. Claim 48 is amended to depend from claim 24 rather than claim 4.

As amended, Claim 48 is directed to a method for identifying a research subject in a group of donors from at least one collection agency by obtaining a plurality of biological samples from a donor, wherein the samples are collected and stored longitudinally. To support this rejection, the Examiner has cited Tacklind (column 5, lines 55-63 and column 6, lines 5-13). The longitudinal data recordation in Tacklind, as discussed above, is a remote reporting system that does regular updates automatically and reports these updates by the telephone system. This is fundamentally different from the sample collection and storage of claim 48, which relates to long-term manual collection of samples over time. To overcome this deficiency, the Examiner

has now cited to Schappert (colum 12, lines 31-36). While Schappert discloses testing biological samples, Schappert does not disclose taking samples that are collected and stored longitudinally. Moreover, the Examiner has not provided a motivation for combining the teachings of Schappert with Tacklind. One of skill in the art would not be motivated to combine the manual collection of biological samples of Schappert with the remote reporting system of Tacklind.

Moreover, Tacklind does not cure the deficiencies of the combined teachings of Barry and Schappert, as discussed above. Tacklind does not teach or suggest using donors from a collection agency to gather biological samples and medical data for use in identifying research subjects. In Tacklind, the patients are already the research subjects. Thus, there would be no motivation to use the data collection system of Tacklind in a method for identifying research subjects.

Claim 49

The Examiner has rejected claim 49 under 35 U.S.C. §103(a) as being unpatentable over Barry in view of Tacklind.

As amended, claim 49, and the claims which depend on claim 49, define a method for creating a database by, among other things, collecting biological sample from a least one donor from at least one collection establishment. As discussed above, Tacklind is directed to instantaneous, ongoing monitoring. Tacklind clearly does not disclose a number of the steps in claim 49, including steps (c), (d) and (e). In particular, there is no mention of deriving proteomic and genomic information from a sample, storing the sample in a location from which it can be

recovered, and associating the data with an identification that can be used to locate the samples. The Examiner has now pointed out that these steps are disclosed in Barry in view of Schappert (column 3, lines 5-8). While Schappert discloses testing biological samples, Schappert does not disclose taking samples longitudinally, much less storing the samples in a location from which the sample can be recovered. In fact, the Examiner has not cited to any references in the present Office Action that disclose storing longitudinally derived samples in a location in which the sample can be recovered and associating medical, proteomic or genomic data with an identifier that can be used to locate the sample. In view of these missing and non-obvious steps, the Examiner is requested to reconsider and withdraw the rejection of claim 49.

Claims 5, 27, and 68

The Examiner has rejected claims 5, 27 and 68 under 35 U.S.C. §103(a) as being unpatentable over Barry in view of Schappert and further in view of U.S. Patent No. 5,915,240 to Karpf. Claim 5 is canceled.

Claims 27 and 68 relate to situations in which the donor is a deferred donor. Applicants acknowledge that the concept of a "deferred donor" was known in the art. As discussed above, Karpf teaches a reference computer system for access to medical information over a computer network. This reference computer system, for example, can be used to look up medical information that must be up-to-date and current such as blood donor deferral criteria. As such, Karpf does not cure the deficiencies of Barry and Schappert discussed above. Karpf does not

teach using the reference computer system for storing medical data from donors in order to identify research subjects.

In view of the basic flaws in the Barry and Schappert references, and the fact that Karpf does not provide the missing gaps in these patents, but only provides the term "deferred donor", the Examiner is requested to reconsider and withdraw this rejection.

Claims 9-10, 14-15, 31-32, and 36-37

The Examiner has rejected claims 9-10, 14-15, 31-32, and 36-37 under 35 U.S.C. §103(a) as being unpatentable over Barry in view of Schappert, and further in view of U.S. Patent No. 6,730,477 to Sun. Claims 9-10 and 14-15 are canceled.

Claims 31-32 are directed to methods wherein the medical data collected comprises pharmacogenomic or genomic data, or proteomic data respectively. Claims 36-37 are directed to methods wherein the criteria for selecting a research subject include pharmacogenomic or genomic data, or proteomic data respectively. In support of this rejection, the Examiner relies on Sun (column 6, line 61 to column 7, line 8; column 7, lines 10-23; and column 8, lines 31-49) for the proposition that medical data comprises pharmacogenomic, genomic or proteomic data. Sun is directed to methods for diagnosing, monitoring and staging breast cancer based on analyzing changes in levels of breast specific genes (BSG) in cells. Applicants do not dispute that medical data may include genomic and proteomic data. However, Sun does nothing to overcome the deficiencies of Barry and Schappert since it provides no information on using the information to

identify a research subject. Accordingly, Applicants request the Examiner to withdraw this rejection

Claims 55-58 and 62-65

The Examiner has rejected claims 55-58 and 62-65 under 35 U.S.C. §103(a) as being unpatentable over Barry et al. in view of Tacklind and further in view of Sun.

Claims 55 to 58 define the nature of the genomic or proteomic information provided by the method of claim 49. Claims 62 to 65 are directed to methods for identifying a genomic or proteomic characteristic which correlates with a disease by creating a database according to claim 49. Accordingly, all of the rejected claims depend on claim 49. As discussed above in the Examiner's rejection of claim 49, neither Barry, Schappert nor Tacklind disclose steps (c), (d), (e), and (f). Sun discloses proteomic/genomic monitoring of BSGs. Accordingly, Sun does not cure the deficiencies of the other cited references and therefore cannot be combined with these references to render obvious these claims.

Claims 17-20 and 39-42

The Examiner has rejected claims 17-20 and 39-42 under 35 U.S.C. §103(a) as being unpatentable over Barry in view of Schappert, as applied to claims 1 and 24 above, respectively. Claims 17-20 are canceled.

The Examiner is respectfully directed to the discussion of the rejection of claim 24 above from which claims 39-42 depend. Claims 39 to 42 relate to methods which utilize a second

database. Given the deficiencies of the Barry and Schappert references, and the requirements of claims 39-42 which recite the additional requirement of a second database, applicants request this rejection be withdrawn.

Conclusion

The present invention is not taught or suggested by the prior art. Accordingly, applicants request respectfully that the rejection of the claims be withdrawn.

Respectfully submitted

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